

subchapter must be destroyed or removed from the official establishment.

(f) Sections 320.1, 320.2, 320.3, 320.4, 320.5, 325.20, and 325.21 apply to operations and transactions not in or for commerce in a State designated under paragraph 301(c) only if the State is also designated under section 205 of the Act and if such provisions are applicable as shown in § 331.6.

(g) Section 321.1(a) of this subchapter will not apply to States designated under paragraph 301(c) of the Act.

(h) Parts 322 and 327 and § 325.3 of this subchapter relating to exports and imports do not apply to operations and transactions solely in or for intrastate commerce.

(i) Part 325 of this subchapter will apply to establishments required to have inspection under § 302.1(a)(2) of this subchapter and to operations and transactions solely in or for intrastate commerce, except as provided in paragraphs (h) and (j) of this section.

(j) Sections 325.4, 325.15, and 325.1(b) of this subchapter will not apply to require a certificate, or evidence thereof, for the distribution solely within any designated State of products that are U.S. inspected and passed and so marked.

[35 FR 19667, Dec. 29, 1970, as amended at 36 FR 12004, June 24, 1971; 41 FR 18089, Apr. 30, 1976; 62 FR 45026, Aug. 25, 1997; 64 FR 56416, Oct. 20, 1999]

**§ 331.4 Control and disposal of non-federally-inspected products in States designated under paragraph 301(c) of the Act.**

Upon the effective date of designation of a State under paragraph 301(c) of the Act, no products can be prepared within the State unless they are prepared under inspection pursuant to the regulations in this subchapter or are exempted from the requirement of inspection under § 303.1 of this subchapter, and no unexempted products which were prepared without any inspection can lawfully be distributed within the State. For a period of 90 days from the effective date of such designation, products which were prepared and inspected and passed under the supervision of a responsible State or local inspection agency can be distributed solely within the State, pro-

vided they are not adulterated or misbranded, except that the official inspection legend is not required. Within the 90-day period, products that have been inspected by the State or local inspection agency may be further prepared and otherwise handled in official establishments required to have inspection under § 302.1(a)(2) of this subchapter or at establishments exempted from the requirements of such inspection under § 303.1 of this subchapter, and may be distributed as provided in this section but otherwise shall be handled in accordance with § 305.4 of this subchapter. Such products shall not bear any [Federal] official inspection legends. After said 90-day period, only federally inspected and passed products may be distributed within the designated State, except as provided in § 303.1 of this subchapter.

**§ 331.5 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of products; application of regulations.**

(a) An establishment preparing products solely for distribution within any State shall be designated as one producing adulterated products which would clearly endanger the public health, if:

(1) Any meat or meat food product prepared at the establishment is adulterated in any of the following respects:

(i) It bears or contains a pesticide chemical, food additive, or color additive, that is "unsafe" within the meaning of sections 408, 409, or 706 of the Federal Food, Drug, and Cosmetic Act or was intentionally subjected to radiation in a manner not permitted under section 409 of said Act; or if it bears or contains any other added poisonous or added deleterious substance which may render it injurious to health or make it unfit for human food; or

(ii) It consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, or unwholesome or otherwise unfit for human food (for example, it was prepared from meat or other ingredients exhibiting spoilage characteristics; or it is, or was prepared from, a carcass affected with a

disease transmissible to humans and its condemnation would be required under part 309 or 310 of the Federal Meat Inspection regulations (9 CFR parts 309, 310) at federally inspected establishments; or it is a ready-to-eat pork product which has not been treated to destroy trichinae as prescribed in §318.10 of this subchapter for products at federally inspected establishments); or

(iii) It has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health (for example if insects or vermin are not effectively controlled at the establishments, or insanitary water is used in preparing meat or meat food products for human food); or

(iv) It is, in whole or in part, the product of an animal that died otherwise than by slaughter; or

(v) Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; and

(2) Such adulterated articles are intended to be or are distributed from the establishment while capable of use as human food.

(b) When any such establishment is identified by a Program Inspector as one producing adulterated product, which would clearly endanger public health under the criteria in paragraph (a) of this section, the following procedure will be followed:

(1) The Program Inspector will informally advise the operator of the establishment concerning the deficiencies found by him and report his findings to the appropriate Regional Director for the Program. When it is determined by the Regional Director that any establishment preparing products solely for distribution within any State is producing adulterated products for distribution within such State which would clearly endanger the public health, written notification thereof will be issued to the appropriate State officials, including the Governor of the State and the appropriate Advisory Committee, for effective action under State or local law to prevent such endangering of the public health. Such

written notification shall clearly specify the deficiencies deemed to result in the production of adulterated products and shall specify a reasonable time for such action under State or local law.

(2) If effective action is not taken under State or local law within the specified time, written notification shall be issued by the Regional Director to the operator of the establishment, specifying the deficiencies involved and allowing him ten days to present his views or make the necessary corrections, and notifying him that failure to correct such deficiencies may result in designation of the establishment and operator thereof as subject to the provisions of titles I and IV of the Act as though engaged in commerce.

(3) Thereafter the Program Inspector shall survey the establishment and designate it if he determines, in consultation with the Regional Director, that it is producing adulterated products, which would clearly endanger the public health, and formal notice of such designation will be issued to the operator of the establishment by the Regional Director.

(c) Products on hand at the time of designation of an establishment under this section are subject to detention, seizure and condemnation in accordance with part 329 of this subchapter: *Provided*, That products that have been federally inspected and so identified and that have not been further prepared at any nonfederally inspected establishment may be released for distribution if the products appear to be not adulterated or misbranded at the time of such release.

(d) No establishment designated under this section can lawfully prepare any products unless it first obtains inspection or qualifies for exemption under §303.1 of this subchapter. All of the provisions of the regulations shall apply to establishments designated under this section, except that the exceptions provided for in §331.3 of this part shall apply to such establishments.